

REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Claims 1-47 are pending in this application.

Claim 1 has been amended to specify a first polymer network interpenetrating a second polymer network. This amendment is supported throughout the specification, and in particular, paragraphs [0048], [0056], [0057], and [0081].

Claim 15 has been amended to specify that the first polymer forms a polymer network which interpenetrates a second polymer network formed by the second polymer. This amendment is supported throughout the specification, and in particular, paragraphs [0048], [0056], [0057], and [0081].

Claim 29 has been amended to specify a first polymer network interpenetrating a second polymer network. This amendment is supported throughout the specification, and in particular, paragraphs [0048], [0056], [0057], and [0081].

Claim 41 has been amended to specify a first polymer network interpenetrating a second polymer network. This amendment is supported throughout the specification, and in particular, paragraphs [0048], [0056], [0057], and [0081].

Claims 46 and 47 have been amended such that Claim 47, which depends from Claim 46, recites a narrower range of hydrodynamic radii. This amendment is for the sake of formality, and is supported by the original claims.

I. Claim Rejections under 35 USC §112

The Examiner has rejected Claims 1, 15, 29, and 41 as being indefinite. The Examiner states that the term “substantially free of shell and core configuration” is not clear, and also that the term “substantially free from dissolved oxygen gas” is not clear.

Applicants respectfully disagree and assert that there are many cases from the U.S. Court of Appeals Federal Circuit (“Federal Circuit”) in addition to Ecolab Inc. v. Envirochem Inc., 60 U.S.P.Q. 2d 1173 (Fed. Cir. 2001) that hold the term “substantial” or “substantially” to be unambiguous and definite as a term of degree.

The instant specification uses the term “substantially free” in the absence of numerical limitations to denote approximation, which is entirely acceptable. See Cordis Corp. v. Medtronic AVE Inc., 67 U.S.P.Q. 2d 1876, 1882-83 (Fed. Cir. 2003) (citing Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 61 U.S.P.Q. 2d 1470 (Fed. Cir. 2002)). In the Cordis case, the phrase “substantially uniform thickness” was considered to be definite and defined as “of largely or approximately uniform thickness.” See id. at 1882. In fact, the Federal Circuit specifically acknowledges that “[t]he term ‘substantial’ is a meaningful modifier implying ‘approximate,’ rather than ‘perfect.’” See Liquid Dynamics Corp. v. Vaughan Co., 69 U.S.P.Q. 2d 1595, 1600 (Fed. Cir. 2004). **“[W]ords of approximation, such as ‘generally’ and ‘substantially,’ are descriptive terms commonly used in patent claims to avoid a strict numerical boundary to the specified parameter.”** See id. (internal quotations omitted).

Requiring an Applicant to utilize numerical limitations rather than terms of degree such as “substantially” is directly contrary to Federal Circuit precedent. In another case, the claim limitation “substantially flattened” was considered unambiguous and the Court rejected any attempts to force a numerical limitation into its definition by the lower court. See Playtex Products Inc. v. Procter & Gamble Co., 73 U.S.P.Q. 2d 2010, 2014-15 (Fed. Cir. 2005). The Federal Circuit in Playtex recognized that the Applicant had not defined the invention at the level of a manufacturing specification and therefore no numerical limitation was required. See id. at 2015.

Moreover, the term “substantially free” has repeatedly been held to be definite when used in claims relating to chemical or biological materials *Bausch & Lomb Inc. v. Alcon Laboratories Inc.* 53 USPQ2d 1353 (U.S. District Court Southern District of New York, 1958); *Deering, Milliken & Co., Inc. v. Temp-Resisto Corporation et al.* 116 USPQ 386 (U.S. District Court Western District of New York, 1999). In *Bausch & Lomb*, the U.S. District Court of the Western District of New York found that the use of the term “substantially” in the context of “substantially inhibit effectiveness of disinfectant in cleansing solution” should not be held indefinite, “even though the term ‘substantially’ does not convey quantifiable standard, since, in the context of microbiology, the term is understood to mean ‘microbiologically significant,’ which would be interpreted by a person of ordinary skill in the art to refer to particular calculable range of reduction in antimicrobial activity.”

The holdings apply to the current situation in that when dealing with large numbers of particles, there may exist a very small percentage of molecules which have adopted unfavorable conformations. The presence of this small percentage of unusual molecules in a solution containing several moles of molecules will not have an impact on the macroscopic behavior of the solution. If the claim were to recite simply “free from shell and core configuration” or “free from dissolved oxygen gas,” one of skill in the art would have to assume that a single instance of shell and core configuration or a single molecule of dissolved oxygen would cause a solution to be outside the scope of the claim. Instead, what is intended is that the solution be free of these elements to the extent that its macroscopic behavior is consistent with the behavior of a solution lacking these elements.

In the instant case, the term “substantially free of dissolved oxygen” describes an essential synthesis condition for all free radical polymerization because oxygen in significant amounts can consume free radicals and terminate polymerization. It is a common practice to use nitrogen, or another inert gas, to constantly purge the solvent and ensure the polymerization occurs under these conditions.

The term “substantially free of shell and core configuration” is significant because it differentiates the currently-claimed IPN nanoparticles from particles which are either poly-(N-isopropylacrylamide) [PNIPA] core-poly (acrylic acid) [PAAc] shell, or PAAc core-PNIPA shell.

The currently-claimed particles are unique in that they comprise an interpenetrating network of two different polymers, PNIPA and PAAc. Therefore, the term “substantially free of shell and core configuration” emphasizes a unique aspect of the current invention.

In summary, the phrases “substantially free of a shell and core polymer configuration” and “substantially free from dissolved oxygen gas” are not indefinite. Applicants therefore respectfully submit that Claims 1, 15, 29, and 41, are allowable under 35 USC §112.

II. Claim Rejections under 35 USC §102

The Examiner has rejected Claims 1-10 as being anticipated by Kubota et al. *Journal of Applied Polymer Science*, 1998, vol. 70, p. 1027-1034 (“the Kubota I Reference”). The Examiner states the Kubota I Reference discloses an aqueous dispersion of hydrogel nanoparticles comprising interpenetrating polymer network (IPN) nanoparticles, a first polymer - poly (-N-isopropylacrylamide), a second polymer – poly(acrylic acid), an aqueous medium, and a drug, wherein the dispersion undergoes a transformation from a low-viscous fluid to a gel when heated to about 34°C.

Applicants respectfully submit that the composition disclosed in the Kubota I Reference is entirely different structurally, and has entirely different properties from, the composition described in the current claims. The Kubota I Reference does not, in fact, disclose an IPN, but rather a first polymer grafted to a network of a second polymer.

The currently-claimed IPN nanoparticles are different from the poly (acrylic acid)-graft-oligo(N-isopropylacrylamide) [PAAc-graft-OPNIPAAm] gel reported by Kubota in terms of polymer chain molecular structure, building blocks, and physical properties.

The PAAc-graft OPNIPAAm taught by the Kubota I Reference is a graft polymer, wherein oligomer PNIPA has been chemically bonded onto a PAAc network. In contrast, PAAc and PNIPA chains are physically tangled within the instantly-claimed IPN nanoparticles. Moreover, the PAAc-graft-OPNIPAAm is a bulk gel, while the instantly-claimed invention is a nanoparticle solution that can gelate at elevated temperature. Therefore, the building block in Kubota’s gel is polymer chains,

while the building block in the instant invention is the IPN nanoparticle. Most importantly, the IPN nanoparticle solution can achieve reverse sol-gel transition at very low concentration.

The current claims recite a composition which consists of nanoparticles which comprise interpenetrating polymer networks of PNIPA and PAAc. In order to further emphasize this difference, Applicants have amended Claim 1 to recite “a first polymer network interpenetrating a second polymer network...”

The composition described in the Kubota Reference consists of a PAAc network PNIPA chains grafted onto it (please see Kubota I Reference, Figure 9). At a higher temperature, the PNIPA chains shrink, but do not change the structure of the PAAc. The PNIPA chains do not form an interpenetrating network with the PAAc network, which makes this composition distinct from the currently-claimed composition.

The changes in the composition which occur at different temperatures further distinguish the two compositions. The interpenetrating polymer network (IPN) particles of the currently-claimed invention separate at below the low critical solution temperature (LCST), while above the LCST, the IPN particles become attractive to each other. This is distinct from the composition taught in the Kubota Reference, which is a bulk gel at any temperature, and wherein the temperature change only makes the PNIPA chains that are grafted to the PAAc bulk gel shrink (please refer to Exhibit 1 and Exhibit 2).

For these reasons, Claims 1-10, as amended, are novel and in condition for allowance.

III. Claim Rejections under 35 USC §103

The Examiner has rejected Claims 1-47 as being obvious over the Kubota I Reference, in further view of Kubota et al. Journal of Applied Polymer Science, 2001, Vol. 80, p.789-805 (“the Kubota II Reference”), in further view of Gan & Lyon (“the Gan Reference”), in further view of Plucktaveesak et al. (“the Plucktaveesak Reference”), and in further view of Hennink & Nostrum (“the Hennink Reference”).

The Examiner states that the Kubota I Reference meets the limitations of Claims 1-28. As described above, Applicants have amended Claim 1. Claim 1, as amended, recites interpenetrating polymer networks which are not taught in the Kubota I Reference. Applicants have also amended Claim 15 to specifically recite, “and wherein the first polymer forms a first polymer network which interpenetrates a second polymer network formed by the second polymer.” The formation of interpenetrating polymer networks is unique to the current invention, and is clearly not present in the Kubota I Reference.

None of the Kubota II Reference, the Gan Reference, the Plucktaveesak Reference, or the Hennick Reference discloses an interpenetrating polymer network.

Applicants therefore submit that none of Claims 1-28, as amended, could be considered obvious over Kubota in further view of the other cited references.

The Examiner has found that Claims 29-40 are obvious in view of the Kubota I Reference in further view of the other cited references.

Applicants have amended Claim 29 to recite “a first polymer network interpenetrating a second polymer network.” As described above, this is clearly distinct from the Kubota I, which describes PNIPAM chains that are grafted to the PAAc. This is structurally different, and behaves differently, than the two interpenetrating networks of the current claims.

None of the Kubota II Reference, the Gan Reference, the Plucktaveesak Reference, or the Hennick Reference discloses an interpenetrating polymer network.

Applicants therefore respectfully submit that Claims 29-40, as amended, would not have been obvious to one of skill in the art over the Kubota I Reference and in further view of other cited references.

Finally, the Examiner has stated that Claims 41-47 are obvious in view of the Kubota I Reference and in further view of other cited references. Applicants have amended Claim 41 to recite IPN nanoparticles which “comprise a first polymer network interpenetrating a second polymer network”, and that this distinguishes the current Claims 41-46 from the Kubota I Reference. As

described in further detail above, the Kubota I Reference does not teach a composition with two interpenetrating polymer networks.

None of the Kubota II Reference, the Gan Reference, the Plucktaveesak Reference, or the Hennick Reference discloses an interpenetrating polymer network.

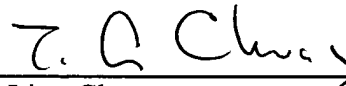
Applicants therefore respectfully submit that Claims 41-46, as amended, would not have been obvious to one of skill in the art over the Kubota I Reference and in further view of other cited references.

IV. Conclusion

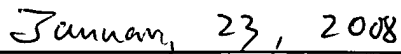
Applicants respectfully submit that, in light of the foregoing comments and amendments, all pending claims are now in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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